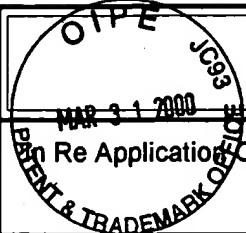


CAU 1632



TRANSMITTAL LETTER
(General - Patent Pending)

Docket No.
480.18-4 (HV)

Re Application Of: **GRUENERT, ET AL.**

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|--------------------------|----------------------------------|------------------------|------------------------|
| Serial No. 09/392,682 | Filing Date SEPTEMBER 9, 1999 | Examiner UNASSIGNED | Group Art Unit 1632 |
|--------------------------|----------------------------------|------------------------|------------------------|

Title: **GENE THERAPY BY SMALL FRAGMENT HOMOLOGOUS REPLACEMENT**

TO THE ASSISTANT COMMISSIONER FOR PATENTS:

APR 04 2000

Transmitted herewith is:

TECH CENTER 1600/2900

1. TRANSMITTAL LETTER;
2. INFORMATION DISCLOSURE STATEMENT;
3. PTO FORM 1449 AND COPIES OF LISTED REFERENCES; AND
4. POSTCARD.

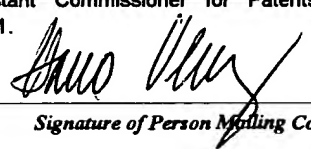
in the above identified application.

- ☐ No additional fee is required.
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Dated: **MARCH 27, 2000**

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CC:

480.18-4



1

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

DIETER C. GRUENERT, ET AL.

Serial No.: 09/392,682

Filed: September 9, 1999

For: GENE THERAPY BY SMALL FRAGMENT
HOMOLOGOUS REPLACEMENT

Art Unit: 1632
APR 04 2000

Examiner:
Unassigned
TECH CENTER 1600/2900

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231 on March 27, 2000.


Hana Verny (Reg. No. 30,518)

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. 1.97(b)

The information disclosure statement submitted herewith is being filed after three months of the filing date of the application and before the mailing date of a first Office action on the merits, whichever event occurs last. 37 CFR 1.97(b).

The citations listed on the attached PTO 1449, along with the copies of enclosed references, provide the background and may be material to the examination of the above-identified application and are, therefore, submitted in compliance with the duty of disclosure in 37 C.F.R. 1.56, 1.97 and 1.98.

Some of the references may have been disclosed in the application and provide either the background for the invention or support for practicing it. The designation of references corresponds to the designation given in the Form 1449.

Reference A. U.S. Patent 4,950,599 issued August 21, 1990 to Wolf Bertling.

Reference Q. ERIC J. SORSCHER et al, Gene Therapy for Cystic Fibrosis Using Cationic Liposome Mediated Gene Transfer: A Phase I Trial of Safety and Efficacy in the Nasal Airway, Human Gene Therapy, 5:1259-1277, October 1994.

Reference P. JAMES M. WILSON et al, Gene Therapy of Cystic Fibrosis Lung Disease Using E1 Deleted Adenoviruses: A Phase I Trial, Human Gene Therapy, 5:501-519, 1994.

Reference Q. NATASHA J. CAPLEN et al, Liposome-mediated CFTR gene transfer to the nasal epithelium of patients with cystic fibrosis, Nature Medicine, Volume 1, Number 1, pp. 39-46 January 1995.

Reference R. RICHARD M. BOUCHER et al, Gene Therapy for Cystic Fibrosis Using E1-Deleted Adenovirus: A Phase I Trial in the Nasal Cavity, Human Gene Therapy 5:615-639, 1994.

Reference S. MITCHELL J. GOLDMAN et al, Gene therapy in a xenograft model of cystic fibrosis lung corrects chloride transport more effectively than the sodium defect, Nature Genetics, Volume 9, pp. 126-131, February 1995.

Reference T. JOE PALCA, The Promise of a Cure, Discover, pp 79-86, June 1994.

Reference U. JOSEPH ZABNER et al, Adenovirus-Mediated Gene Transfer Transiently Corrects the Chloride Transport Defect in Nasal Epithelia of Patients with Cystic Fibrosis, Cell, Vol 75, pp 207-216, October 22, 1993.

Reference V. TERRENCE R. FLOTTE et al, An improved system for packaging recombinant adeno-associated virus vectors capable of in vivo transduction, Gene Therapy, 2, pp 29-37, 1995.

Reference W. Gene therapy for cystic fibrosis, Nature Medicine, Volume 1, Number 3, pp 182, March 3, 1995.

Reference X. DEBORAH ERICKSON, Genes to Order, Scientific American, pp 112-114, June 1992.

Reference Y. JAMES M. WILSON, Vehicles for gene therapy, Nature, Vol 365, pp 691-692, October 21, 1993.

Reference Z. ERIC ALTON & DUNCAN GEDDES, A mixed message for cystic fibrosis gene therapy, Nature Genetics, Volume 8, pp 8-9, September 1994.

Reference AA. JAMES J. LOGAN et al, Cationic lipids for reporter gene and CFTR transfer to rat pulmonary epithelium, Gene Therapy 2, pp 38-49, 1995.

This Information Disclosure Statement under 37 C.F.R. 1.56, 1.97, and 1.98 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

This application relies, under 35 U.S.C. § 120, on the earlier filing date of prior application Serial No. 07/933,711, filed on

August 21, 1992.

Copies of the Information Disclosure Statement and form PTO 1449 submitted in the prior application are enclosed. The references in the enclosed prior application's PTO 1449 were submitted to and/or cited by the Office in the prior application and therefore are not required to be provided in this application.

If fees are required with the filing of these documents, the Commissioner is authorized to charge such fees to Deposit Account No. 16-1331.

Respectfully submitted,

Date: March 27, 2000



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UC Case No. 92-070-4
Atty Dkt. 480-18.4 (HV)